Exhibit 7

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendant.	Case No. 2:22-cv-00223-Z

DECLARATION OF KATHERINE McHUGH, MD

I, Katherine McHugh, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury that the following is true and correct to the best of my knowledge and belief, and that these statements are based on my personal knowledge as well as information made known to me in the course of my medical practice:

1. I am a board-certified Obstetrician-Gynecologist ("Ob-Gyn") physician at Women's Med Health Center Indianapolis and Partners in Abortion Care in College Park, Maryland. I also serve as an Associate Professor of Clinical Ob-Gyn at the University of Cincinnati, and owner of Indiana Pelvic Pain Specialists. In my day-to-day practice, I participate in both inpatient and outpatient management of pregnancies, which includes treating patients experiencing complications that arise during pregnancy and patients who wish to terminate their pregnancy. I provide abortion care in Indiana, Ohio, and Maryland, as permitted under the relevant state laws. I graduated from Indiana University School of Medicine in Indianapolis in 2011 and completed my residency in 2015. I joined the faculty of Indiana School of Medicine Department of Ob-Gyn upon graduation.

2. In my current position at the University of Cincinnati, I teach obstetrics and gynecology to residents, fellows, and medical students, and collaborate with nurses, midwives, and practitioners of many other disciplines. While at Indiana University, I served as one of the Associate Residency Program Directors and developed state-wide training programs for improving health outcomes of both mothers and babies. I have held multiple national Board positions, including on the Executive Board of the American College of Obstetricians and Gynecologists (ACOG) and Physicians for Reproductive Health. In addition to continuing to practice in an academic setting and teaching learners, I also started a small private practice treating patients with chronic pelvic pain, a topic on which I have published national guidance through ACOG. In these roles, I have delivered thousands of healthy babies to healthy parents over my twelve years of professional practice, as well as supported hundreds of families through the challenging decisions around pregnancy complications, terminations, and infertility.

3. I am familiar with the medication Mifepristone, have used it in the course of my practice, and continue to do so. I am also a certified prescriber of Mifeprex under the Mifeprex REMS Program.

4. For patients seeking to terminate an early pregnancy, I offer a choice between a medication regimen or a surgical procedure. Until 10 weeks gestation, pregnancy termination by medication abortion is an option. This regimen consists of Mifepristone 200mg orally followed by Misoprostol after 24-48 hours. These medications induce bleeding and shedding of the early pregnancy without need for instruments or procedures. Surgical abortion is performed anytime the patient declines medication abortion or if the patient is unstable and needs urgent intervention, or if the patient is unable to reliably attend follow-up appointments or seek urgent medical attention. While the

specifics of the procedure vary based on gestational age, the patient has a quick and simple procedure to stretch the cervix and remove the pregnancy tissue from the uterus.

5. Mifepristone is a small pill that, in the clinics where I practice, is dispensed at the clinic as required by state law. In both Indiana and Ohio, Mifepristone must be administered by an in-person physician, who watches the patient swallow the pill in the office. (Of note, this observation process has no medical indication but is required due to state regulation.) In the clinics where I practice in these states, Misoprostol is likewise dispensed at the clinic providing abortion care, and the patient takes it at home 24-48 hours after the Mifepristone. By contrast, in Maryland there are no laws mandating in-person observation of a patient taking Mifepristone or that it be dispensed by a physician. Patients in my Maryland practice are evaluated and counseled by me or one of my physician partners, after which the patient takes Mifepristone with a Registered Nurse prior to discharge home. Telehealth is also an option for patients in Maryland, whereas medication abortion provided via telehealth was specifically banned by Indiana and Ohio. After taking Misoprostol, the patient is expected to experience bleeding and cramping starting within a few hours, during which the pregnancy tissue passes. Medication abortion is 96-98% effective with very low rates of complication. ACOG Practice Bulletin, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

6. I have found that patients often prefer a medication abortion for various reasons, including being able to plan their recovery time around family schedules, work, and other responsibilities, maintaining privacy, the perception that it is a more natural end to the pregnancy, as well as avoiding the more invasive surgical procedure. Based on my years of practice, my understanding of the published medical literature, and the requirement, described above, to ensure informed consent when counseling patients, I counsel my patients that medication abortion is safe and very

effective, making it an excellent choice for early pregnancy termination, and that, although medication abortion takes longer than a surgical abortion, the patient has more control over the process. The patient must be able to assess their symptoms and obtain transportation to a medical facility, should that become necessary, in order to proceed with medication abortion. If patients are unable to assess their symptoms or get medical help in the case of an emergency, the patient is not a candidate for medication abortion and must choose between surgical abortion and continuing the pregnancy. I also counsel the patients on the high safety and efficacy of medication abortion, as well as the preservation of future fertility and a discussion of any contraceptive needs. In particular, I have found that patients who are victims of abuse, including rape and incest, may find medication abortion to be a less invasive choice that avoids retraumatizing them and returns control over their bodies rightfully back to the victim.

7. Prior to prescribing Mifepristone, legal and medical ethics require providers, such as myself, to ensure that appropriate informed consent is obtained and that shared decision-making is effectuated by the patient and any family or friends the patient chooses. In ensuring that patients are fully informed when choosing among options, I always speak with the patient alone to screen for coercion or doubt in the decision. I provide the patient with the Mifepristone Medication Guide and Patient Agreement, answer any questions, and ensure the patient signs the Patient Agreement. We discuss the patient's options, based on medical history and gestational age, as well as the risks and benefits of each option, and answer all questions the patient has around the process. Included in all discussions of risk are the specific risks with each medication. Mifepristone is well studied in pregnancy termination and, as noted, has the expected effects of contributing to uterine cramping and bleeding. Mifepristone is not used in patients with known allergy to Mifepristone, an intrauterine contraceptive device in place, or an ectopic pregnancy (a pregnancy implanted outside

of the uterus). Mifepristone is also avoided in patients with bleeding disorders, with steroid-dependent medical conditions, and in patients taking blood thinning medications. Medication abortion with Mifepristone is much safer in patients with significant medical problems or complicated surgical histories which would make either surgical abortion or anesthesia more risky than normal. Patients who are very young also benefit from medication abortion because it avoids the need for a pelvic exam.

8. The information I provide to my patients is based on my years of training and experience both teaching new doctors and treating patients. I understand that all medications and medical procedures carry risks, including rare adverse events, and convey that understanding to patients as part of my regular medical practice. Mifepristone allows for the safe expulsion of pregnancy tissue without the additional risks of surgery or instruments, and allows patients the flexibility of timing the bleeding and cramping as they desire. Additionally, there is a high likelihood of success, up to 99.7% depending on gestational age, with increasing success correlating to decreasing gestational age. Complications of medication abortion are extremely low. Side effects found when Mifepristone is combined with Misoprostol include, in addition to bleeding and cramping, fevers or chills (32-69%), nausea (43-66%), dizziness (28-39%), vomiting (23-40%), diarrhea (23-35%), and headache (13-40%). These side effects are expected, however, as is the case with most or all medications, and are not considered to be complications. Need for transfusion (<0.1%) and need for surgical evacuation (<1%) are the most commonly reported adverse events. The notable adverse outcome that is possible with Mifepristone is possible teratogenic effects (causing birth defects or developmental malformations) on the fetus if the patient elects to continue the pregnancy after taking Mifepristone. All of these possibilities are extensively discussed with the patient, both verbally and in writing, prior to Mifepristone administration. Given the low incidence of adverse

events from Mifepristone, combined with its high efficacy, medication abortion is among the safest outcomes for a person desiring pregnancy termination. Of note, the mortality rate of legal, induced abortion is estimated to be 0.6 per 100,000 procedures, while the general mortality rate of continuing pregnancy is 8.8 per 100,000 live births, making legal abortion approximately 14 times safer than continuing pregnancy to delivery.

9. Healthcare providers, such as myself, rely on FDA to make a careful assessment of the risks and benefits of a medication and determine safety and efficacy; FDA's expert judgment informs our practice in treating individual patients. With the guidance of the FDA, clinicians make critical decisions about medications based on safety and efficacy. Interfering with FDA's process for assessing the risks and benefits associated with distribution of particular medications places patients and clinicians at risk.

10. As an example of the use of Mifepristone for my patients, I provide approximately 10 medication abortions per week in Indiana. While every patient's situation and reasoning is unique, there are certainly themes. I recently saw a patient at 7 weeks gestation who confided that her partner was physically, emotionally, and sexually abusive, and she needed her abortion to include bleeding so her partner would know she was not pregnant. When I called her a few weeks later, she spoke to me from the women's shelter, having successfully moved out and escaped her abuser.

11. Medication abortion also minimizes contact with the medical system. A woman told me that she didn't trust the medical system since her sister had died during childbirth, something the patient didn't believe could still happen in the United States. She chose medication abortion because it allowed her to be in control of what went into her body and minimized the number of people wanting to touch, examine, or perform a procedure on her body.

12. Another recent patient was at 9 weeks gestation and visited me the day before she was leaving for college. Though not a minor, she was accompanied by her mother, who supported the patient in her desire to prioritize her education before starting a family.

13. As a result of state-based abortion bans, patients are forced to travel to obtain abortion care, sometimes many states away, like the patient I saw recently from Louisiana. She talked about how she planned to leave immediately after taking the Mifepristone to start her 13-hour drive home so that she could rest in her own bed when the bleeding and cramping started.

14. Finally, patients sometimes tell us that their pregnancy is the result of rape, and while the thought of a pelvic exam and instruments in their vagina is further traumatizing, removing the pregnancy returns their body to their control.

15. I understand that Plaintiffs in this suit have asked the Court to revoke FDA's approval of Mifepristone. In my opinion, granting that request would cause overwhelming harm to patients and the medical practice. Up to 60% of abortions in the United States under 10 weeks are medication abortions, and decades of experience and an extensive body of high-quality medical literature unequivocally demonstrate that Mifepristone is safe and effective. Patients seeking medical care for their pregnancies deserve empathy and evidence-based medical care. Removing FDA approval of Mifepristone will result in delays in returning to work and family obligations, prolonged symptoms such as pain and bleeding, and an increase in surgical intervention. States with abortion bans and restrictions after the *Dobbs v. Jackson* decision are already struggling to meet the need for reproductive care for their pregnant citizens. Adding yet another barrier to safe, legal abortion care will have a harsher impact on those states, including women who must travel from those states to obtain reproductive care, and worsen the alarming disparity we see in maternal mortality, infant mortality, and childhood health outcomes. Withholding any medication that is

known to be a safe and effective treatment for the presenting problem violates the medical code of ethics and oath which medical providers swear to uphold. Mifepristone is a critical, safe, and effective step in medication abortion.

Dated: January 13, 2023

Katherine McHugh, MD